K013387

JAN 8 2002

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 Web Viewer

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

October 10, 2001

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5 Web Viewer

COMMON NAME:

Remote monitoring device

CLASSIFICATION NAME:

The following Class II classification appears applicable:

System, network and communication, physiological monitors	870.2910

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5 Web Viewer is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Network and Central and Information Center (510(k) number: K000647).

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DEVICE DESCRIPTION as required by 807.92(a)(4)

The Web Viewer is a supplementary monitor based on the WWW-browser technology. It is meant to be used for remote viewing of real-time patient information and trends from a generic personal computer connected the hospital LAN. The PC uses standard browser software to gain access to the Web Server which contains the Datex-Ohmeda specific Web Viewer software. The Web Server in turn receives the patient data from Datex-Ohmeda S/5 Central serving the Datex-Ohmeda S/5 Network. The hospital is responsible for ensuring a secure and functional interface between the Datex-Ohmeda S/5 Network and the Hospital LAN, by utilizing for example a gateway, router, switch or firewall. If the Web Viewer clients are not connected to a hospital Intranet, a regular hub can be used instead.

INTENDED USE as required by 807.92(a)(5)

The Datex-Ohmeda S/5 Web Viewer is intended to be used for viewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda S/5 Web Viewer displays information received from other networked devices. It is comprised of an S/5 Web Server and S/5 Web Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the networked devices in Datex-Ohmeda Network and S/5 Web Viewer clients. The S/5 Web Viewer client runs on a generic computer that is connected to the hospital local area network. The Datex-Ohmeda S/5 Web Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices.
The Datex-Ohmeda S/5 Web Viewer will be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 Web Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5 Web Viewer is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Network and Central (K000647).

The structure and functionality of the Datex-Ohmeda S/5 Web Viewer corresponds to the structure and functionality of the Datex-Ohmeda S/5 Network and Central (predicate) as follows:

The Datex-Ohmeda S/5 Web Viewer can show real-time curves, numeric information and visual alarms from bedside monitors just like the predicate Datex-Ohmeda S/5 Network and Central (K000647). In contrast to the predicate Datex-Ohmeda Network and Central the Datex-Ohmeda S/5 Web Viewer also offers graphical and numerical trends but does not provide audible alarms. Displayed information is always the same as on the source monitor. The S/5 Web Viewer can display data from one monitor at a time only, whereas the S/5 Central can provide centralized monitoring for up to 32 monitors at a time.

The Datex-Ohmeda S/5 Web Viewer is an extension of the Datex-Ohmeda S/5 Network and Central. It offers distributed monitoring in form of an additional viewing tool. The Datex-Ohmeda S/5 Web Viewer is not intended as a primary alarm source. It does not adversely effect the safety and effectiveness of the system.

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The indications for use of the Datex-Ohmeda S/5 Web Viewer are nearly the same as for the Datex-Ohmeda Network and Central (K000647). Both are used by a clinician, a nurse or doctor, to monitor patients but the environment for use is different. The Central is used near the care area but the S/5 Web Viewer can be used anywhere that is connected to the hospital LAN, for example in a doctors office. The information shown in both the S/5 Web Viewer and the predicate are copies from corresponding bedside monitors. The Datex-Ohmeda S/5 Web Viewer and the predicate Network and Central (K000647) can both be used for viewing or otherwise processing of information from several bedside monitors or other networked devices.

The physical network and the PC hardware components used by the S/5 Web Viewer are the same as in Datex-Ohmeda Network and Central.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5 Web Viewer complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- EN60950: 1995 (IEC950 2nd edition) - Safety of information technology equipment, including electrical business equipment
- EN 55022: 1994 (IEC-CISPR 22) – Information technology equipment - Radio disturbance characteristics. Limits and methods of measurement
- EN 55082-1: 1991 (IEC 801-2, IEC 801-3, IEC 801-4) – Electromagnetic compatibility - Generic immunity standard
- IEC 60601-1-2, Radiated Emission (IEC-CISPR11)
- IEC 60601-1-2, Immunity to Electrostatic Discharges (IEC-61000-4-2)
- EN 1441, Medical devices - Risk analysis
- IEC 60601-1-4
- CAN/CSA-C22.2 No 950: Information Technology Equipment Including Electrical Business Equipment
- UL1950: Information Technology Equipment Including Electrical Business Equipment
- ISO/IEC 8802-3 (ANSI/IEEE 802.3), EIA/TIA-568, EIA/TIA-TSB40, international network cabling standards

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5 Web Viewer as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 2002

Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492

Re: K013387
Trade Name: S/5 Web Viewer
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MSX
Dated: October 11, 2002
Received: October 12, 2002

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

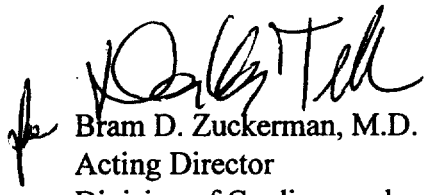
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013387

Device Name: Datex-Ohmeda S/5 Web Viewer

Indications For Use:

The Datex-Ohmeda S/5 Web Viewer displays information received from other networked devices. It is comprised of an S/5 Web Server and S/5 Web Viewer clients.

The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the networked devices in Datex-Ohmeda Network and S/5 Web Viewer clients. The S/5 Web Viewer client runs on a generic computer that is connected to the hospital local area network.

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The Datex-Ohmeda S/5 Web Viewer is not a primary alarm source.
The device is for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013387